REMARKS

This is in response to the Final Office Action mailed 5 October 2007. Please consider this paper a petition for a two month extension of time. Please also consider this paper as a Request for Continued Examination. Please charge any required fees to have this amendment and Request for Continued Examination Entered.

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1-18, 20, 22-34, and 36-47 are pending in the application. Basis for the amendment of claims 1, 27, 46 and 47 can be found in the present specification including at cancelled claim 35. No new matter has been added.

The rejection of claims 1-4, 7, 10, 11, 13, 15, 22 and 27 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,858,410 (Muller 410) is respectfully traversed. The claimed invention is not anticipated by Muller 410 for the reasons of record and for the following reasons.

All of the pending claims require "an anhydrous or water-reduced dispersion medium containing less than 80 wt.% of water" as the dispersion medium, which was originally recited in claim 35. The Examiner admits that claim 35 is not anticipated by Muller 410 since it was not included in the Section 102 rejection. In view of the differences between Muller 410 and the claimed invention, withdrawal of the Section 102 rejection is respectfully requested.

The rejection of claims 1-20 and 22-47 under 35 U.S.C. § 103 as being unpatentable over WO 98/14174 (Desai) in view of U.S. Patent No. 5,104,674 (Chen) is respectfully traversed. The claimed invention is not obvious over Desai in view of Chen for the reasons of record and for the following reasons.

The experimental evidence of record rebuts any prima facie case of evidence raised by the Examiner. As discussed previously, Applicants have now found that during high-pressure homgenization using a piston-gap homogenizer, water vapor is created in the form of bubbles, which subsequently implode, otherwise known as cavitation. The resulting implosion shock waves lead to particle diminution.

However, many materials are destroyed, melted or otherwise undesirably altered by these violent shock waves (cavitation). See page 3, last paragraph to page 4, first paragraph, in the present translated application.

Applicants have solved these problems by providing a far more gentler method of obtaining the same particle size without using the implosion shock waves (i.e. substantially avoiding cavitation):

1) reducing or eleminating the use of water; and/or

2) reducing the temperature of the medium being homogenized.

As discussed above, prior to the present invention, it was believed throughout the art that cavitation was required as the main source of diminution. As a consequence high pressure homogenization is generally described in water and especially increased effectiveness is claimed when homogenizing at higher temperatures. The reason for the increased efficiency at higher temperatures is the increased vapour pressure of water at higher temperature which provides increased cavitation. Therefore, the general teaching is the need to use water at higher temperatures to provide increased cavitation formation from water vapor to thereby provide particle diminution.

Contrary to this teaching, according to the present invention high-pressure homogenization using a piston-gap homogenizer is performed in media other than water (anhydrous) or water reduced (less than 80% wt.), and/or at lower temperatures to substantially **avoid cavitation** from water vapor. Surprisingly, it has been found that even without presence (anhydrous) or presence of reduced amounts of water, still a comparable size diminution can be obtained. Thus, it is believed, without being bound to any theory, that effects other than cavitation are responsible for the observed diminution action. Contrary, to the general knowledge in the art, Applicants have found that cavitation is not the dominating diminution principle in the present invention. This is further supported by performing homogenization at lower temperatures, e.g. at 0° Celcius or below. A surprisingly similar efficiency in diminution is observed, which is contrary to the general beliefs in the art. Furthermore, there is no increase of homogenization cycles required so that effectiveness of the high-pressure homogenization is about the same compared to

homogenization in water using primarily cavitation. This enables processing of hydrolysis sensitive drugs. Please see pages 4-6 of the originally filed application, which further describes the unexpected advantages of the claimed invention.

The cited references do not teach or suggest these unexpected results. Neither of the cited references, alone or in combination, disclose the unexpected advantages associated with avoiding cavitation in a high-pressure homogenzation method using a piston-gap homogenizor. For these reasons alone, the Section 103 rejection should be withdrawn.

Even if Chen is combined with Desai, the theoretical combination of references does not teach or suggest the claimed invention for the following reasons. The Examiner argues that "Chen teaches an anhydrous dextrose or dried corn syrup (col. 41, lines 36-45)". However, the complete paragraph at column 41, lines 36-45 of Chen actually teaches:

> The food commonly and usually known as "Milk Chocolate" or "Milk Chocolate Coating" is the solid or semi-plastic food composed basically of chocolate liquor intimately mixed and ground with milk solids and one or more of the sugar ingredients (cane or beet sugar, partially refined cane sugar, anhydrous dextrose or dried corn syrup). Milk chocolate candy incorporating up to about 10 weight percent of a microfragmented xanthan/protein complex dispersion (solids basis), may be provided which has significantly reduced calorie content.

This disclosure in Chen actually teaches that the "microfragmented xanthan/protein complex dispersion" can be added to conventional milk chocolate. This paragraph does **not** teach that milk chocolate is made using high pressure homogenization. This paragraph also does not teach that "anhydrous dextrose or dried corn syrup" (which is used in the conventional milk chocolate) can be used as a dispersion medium in place of the water dispersion medium used to make the "microfragmented xanthan/protein complex dispersion".

See the paragraph starting at column 5, line 35 of Chen, which teaches that:

> The present invention is directed to the provision of **aqueous dispersions** of insolubilized, microfragmented polysaccharide/protein complexes which are useful as a nutritious bulking, viscosity or texture control agent and having desirable rheological characteristics of stable lubricity and creamy mouthfeel. [Emphasis added.]

Chen clearly teaches that the dispersion medium is only water. Reading the language at column 41, lines 36-45 of Chen with the entire teachings of Chen, it is very clear that the "anhydrous dextrose and corn syrup" are only ingredients in conventional milk chocolate, and are surely not used to replace the water dispersion medium used to prepare the "microfragmented xanthan/protein complex dispersion."

The Examiner also cites Example 15 of Chen as teaching "a mixture is cold homogenized using a single-piston homogenizer." First, Applicants respectfully submit that Example 15 of Chen actually teaches using water as the dispersion medium. See column 60, line 49-55, which discloses using the "xanthan/protein complex" was made according to Example 3, using water as the dispersion medium, and that complex is dispersed in water. At column 61, line 10-35, teaches adding water and mixing using a Lanco high speed mixer, passing the ingredients through a HTST and homgenizer (Manton-Gaulin). Clearly, water is the dispersion medium. Furthermore, Chen teaches that **the temperature was raised to 65.5°C before homogenization**. See column 61, line 17. Thus, the mixture was not "cold homogenized" as stated by the Examiner. Chen teaches nothing more than conventional homogenization using cavitation.

The combination of Chen and Desai teaches using water as the dispersion medium, which is conventional homegnization, and to use cavitation, for the reasons above and for the following reasons. Cavitation is disclosed in Chen at column 60, lines 10-11. Thus, Chen in fact teaches away from the claimed invention.

Desai also teaches away from the claimed invention. See page 18, lines 16-19 of Desai, where Desai describes "[a]cceptable methods of homogenization include processes imparting high shear and **cavitation**..." As discussed above, Chen also teaches to use cavitation. Furthermore, it is well known in the art that piston-gap homogenizers are used under conditions to form cavitation when water is the dispersion medium. Thus, the combination of Chen and Desai teach to use conventional cavitation, even if a piston-gap homogenizer is used in the theoretical method of Chen and Desai, which is in a direction away from the claimed invention. For this reason alone, the Section 103 rejection should be withdrawn.

Present claims 46 and 47 recite particles of "5.6 μm or less," which are not

included in Chen's particle range of 2 to 10 microns or Desai's particle ranges. For this reason alone, the Section 103 rejection of claims 46 and 47 should be withdrawn.

Present claims 10-12, 14 and 44 specifically recite using dispersion mediums other than water. Desai and Chen both require water. Thus, the combination of Desai and Chen cannot possibly teach or suggest the subject matter of claims 10-12, 14 and 44. For this reason alone, the Section 103 rejection of claims 10-12, 14 and 44 should be withdrawn.

Claim 25 recites carrying out the process with the exclusion of oxygen. None of the cited references teach or suggest this limitation. For this reason alone, the Section 103 rejection of claim 25 should be withdrawn.

Claim 26 recites degassing the dispersion medium before use. None of the cited references teach or suggest this limitation. For this reason alone, the Section 103 rejection of claim 26 should be withdrawn.

Claim 41 and 42 recite gassing the matrix material and medium with inert gases. None of the cited references teach or suggest this limitation. For this reason alone, the Section 103 rejection of claims 41 and 42 should be withdrawn.

In view of the many differences between the claimed invention and the theoretical combination of Desai and Chen, and the unexpected advantages of the claimed invention, withdrawal of the Section 103 rejection is respectfully requested.

In view of all of the rejections of record having been addressed, Applicants submit that the claimed invention is in condition for allowance and Notice to that effect is respectfully requested.

Respectfully submitted,
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